

ATTACHMENT C**SUMMARY OF MDR REPORTING REQUIREMENTS****Individual Adverse Event Reports - 803.50****General Requirements:**

- Manufacturers must submit death, serious injury, and malfunction reports within 30 days after they become aware of a reportable event.
- The information can come from any source.
- Devices that "may have caused or contributed" to a death or serious injury; or a malfunction that would be likely to cause or contribute to a death or serious injury must be reported.

Reasonably known:

- Firms must provide all information that is reasonably known to them. FDA considers the following to meet this standard, i.e., any information:
 - that can be obtained by contacting a user facility, distributor, and/or other initial reporter,
 - in the manufacturer's possession,
 - that can be obtained by analysis, testing, or other evaluation of the device.

Information required to be reported:

- The form FDA 3500A is the primary reporting form for death, serious injury and malfunction events. With the exception of drug or biologic related items, all the fields must be completed or have an entry (NA, NI, or UNK) indicating why the information could not be obtained.

Missing Information:

- Manufacturers are responsible for obtaining and providing FDA with any information that is missing from reports that are received from user facilities, distributors, and other initial reporters.
- If a firm cannot provide complete information, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information.
- Any required information not available at the time of the report, obtained at a later date, must be forwarded to FDA in a supplemental report within one month of receipt.

Investigation:

- Manufacturers are responsible for investigating and evaluating the cause of each event.
- These investigations must follow the requirements in 21 CFR 820.198 and provide the information required on form FDA 3500A, Block H.6, H.7, and H.9.

Five-Day Reports - 803.53:

- Manufacturers must submit a five-day report on form FDA 3500A within five days under the following two conditions:
 - a. They become aware that an MDR reportable event, from any source, requires remedial action to prevent an unreasonable risk of substantial harm to the public health.

OR

- b. They receive an FDA written request for the submission of five-day reports.

Baseline Reports - 803.55:

- Manufacturers are required to submit a baseline report on FDA 3417 form when the device model is first reported under 803.50.
- Baseline Reports must be updated annually (if information changes) on the firm's scheduled registration date, as required by Part 807.21.

IMPORTANT NOTE: The following MDR requirements have been stayed or revoked:

1. Certification, 21 CFR 803.57.
2. Baseline Reports, only sections 21 CFR 803.55(b) (9) and (10), which correlate to items 15 and 16 on the Baseline Report form, FDA 3417.

Supplemental Reports - 803.56:

- Manufacturers are required to submit, within one month after receipt any required information regarding deaths, serious injuries, and malfunctions that was not available to them when the initial report was submitted.

GENERAL MDR GUIDANCE

This document provides general guidance regarding the reporting of adverse events required by the Medical Device Reporting (MDR) Regulation.

A. PER SE RULE

This requirement no longer exists. Therefore, the submission of an event by a health care professional does not require the manufacturer to report the event based solely on the statements of a health care professional. The event must meet the reporting criteria in MDR to qualify as a reportable event.

B. REPORTING TIME FRAMES

Firms now have up to 30 CALENDAR days after they become aware of a device related death, serious injury or malfunction before they are required to submit a report to FDA.

C. FIVE-DAY REPORTS

Five-day reports are required in two circumstances. First, they are required if a manufacturer becomes aware that a reportable event, from any source of information, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Second, five-day reports are required when a manufacturer becomes aware of an MDR reportable event for which FDA has requested a five-day report.

D. NON-REPORTABLE EVENTS

Firms must submit MDR reports when the reported information reasonably suggests an association between one of its devices and a reportable death, serious injury or malfunction. Under some circumstances, an adverse event may appear to trigger the requirement of submission of an MDR, but because information reveals the device did not cause or contribute to the death or serious injury, no MDR is required. Thus as described below, a manufacturer will have to investigate the event in order to know if it should be reported.

A firm is required to submit an MDR report when it becomes aware of information reasonably suggesting that an event meets the criteria for reporting a Death, Serious Injury, or Malfunction. For example, a hospital informs a manufacturer that its device has failed and, as a result, a patient died. At this point, the firm has become aware of information that reasonably suggests they are in receipt of a reportable MDR event.

Next, the firm must investigate the report to determine its cause. Both the QS Regulation and MDR require investigation of complaints. During its investigation a firm may become aware of information that changes the initial report's conclusions. For example, the firm may find that its device was not involved in the death and could not have caused or contributed to the death. In these instances the firm would document the information that changes the association between

its device and the death. No report would be required if the death or other facts turn out to be incorrect. But, if the firm becomes aware of the identity of the device/firm that was associated with the death, the firm is responsible for forwarding the information to the FDA.

However, if the firm's investigation does not change the alleged association between the device and the death, the event must be submitted as an MDR report. In addition, if the firm's investigation produces information that would cause a person who is qualified to make a medical judgment to reach a reasonable conclusion that the device did not cause or contribute to a reportable MDR event - no report is required. Translation - if a firm decides NOT to report an apparent device-related death, serious injury or malfunction - this decision must be made by a person that the regulation recognizes as qualified to make a medical judgment, i.e., a physician, nurse, risk manager, or biomedical engineer. Using the example from above, if the firm's investigation yields an autopsy finding that the patient died from cancer – not the device - the firm could decide NOT to report as long as the decision is consistent with the regulation:

1. There is documented information that changes the association between the death and the device,
2. The decision is made by a person who is qualified to make a medical judgement, and
3. The conclusion reached by the person in item two is reasonable.

PLEASE NOTE THE FOLLOWING:

- Firms ARE NOT required to have every MDR report reviewed by a person qualified to make a medical judgement and/or a person with a medical degree or training. Individuals who are not qualified to make a medical judgement can review MDR reports and make decisions on the basis of facts but they cannot make decisions NOT to report MDR events that require medical judgement.
- In lieu of in-house or on-site qualified medical personnel or individuals qualified to make a medical judgement the firm may use consultants.
- When reviewing a non-reportable event validate and document the credentials of the individual making these decisions as well as the decision not to report the event.

E. INVESTIGATION

Firms are required to investigate EVERY device related death, serious injury and malfunction in accordance with QS regulation, 820.198. Failure to comply with this provision is a violation of BOTH the QS regulation and MDR. Manufacturers are also required to VERIFY information on each form FDA 3500A as well as make a good faith effort to obtain information that is missing/not provided by the reporter. If the firm cannot obtain the missing information, the MDR complaint files shall contain an explanation of why the information could not be obtained as well as documentation of the firm's efforts to obtain the missing information.

F. REASONABLY KNOWN INFORMATION

FDA considers information that can be obtained by contacting the reporter to be in the possession of a firm, and considers information that can be obtained by analysis, testing, or other evaluation of a device to be information that a firm is expected to REASONABLY know, obtain and report.

G. REASONABLY KNOWN/GOOD FAITH EFFORT

A firm must demonstrate that it exercised "good faith" in any failed attempts to obtain required data that is missing, incorrect, or that FDA considers to be reasonably known. While the concept of good faith is generally considered to be equivalent to "due diligence", CDRH has not developed a standard. However, the firm's procedures for obtaining missing information should appear under the "Internal Systems" section of its written MDR procedures. In addition, the Center believes that the parameters of good faith effort must, at a minimum, comport with the level of risk/nature of the device associated with the event being investigated.

H. SERIOUS INJURY

The interpretation of what constitutes a serious injury can be subjective and complicate the enforcement of MDR. The "unanticipated temporary impairment" part of the former serious injury definition has been rescinded, thus alleviating a source of subjectivity. In addition, the requirements that intervention be "immediate" and the concept of "probability" have also been removed from the serious injury definition.

The current MDR regulation states that a serious injury is an "injury or illness." This literally means that there has to be an injury that is life-threatening, results in permanent impairment/damage, or necessitates medical/surgical intervention to preclude permanent impairment/damage in order for an event to be reportable as a serious injury. If there is no injury attributable to the device, then there is no serious injury report, however, the event may qualify as an MDR reportable malfunction depending upon the circumstances.

The Center may decide to clarify the definition of serious injury. These categories will be provided to the field and the industry through MDR guidance documents and/or letters, as necessary.

I. MALFUNCTIONS

Malfunction reporting decisions have been the subject of concern by both industry and the FDA. Basically, a malfunction is an event that is likely to cause or contribute to either a death or serious injury, but some circumstance prevented the injury or death from occurring. These events are very important since they represent "potential" deaths or serious injuries and provide the Agency with the opportunity to be proactive in reducing risks. Not all malfunctions, however, are MDR reportable events.

If a malfunction is not reportable as an MDR, it may be a complaint and thus subject to the QS complaint handling requirements. Determining if an event is a reportable malfunction involves answering a number of questions including:

1. Is the event device-related?
2. Has the device failed to perform its intended function or meet its performance specifications?
3. Is this failure likely to cause or contribute to a death or serious injury if the event were to happen again?

There is a presumption in the MDR regulations that if the event happened once it can happen again. The determination of whether to submit a report should be based on the potential outcome. For example, if this malfunction were to occur, how would it affect the patient? If the answer is "the malfunction is likely to cause or contribute to death or serious injury" then the event is reportable. The preamble to the MDR regulations (Federal Register: December 11, 1995, Volume 60, Number 237, pages 63577-63607) offers the following guidance for determining circumstances in which malfunctions should be reported:

1. The chance of a death or serious injury occurring as a result of the recurrence of the malfunction is not remote;
2. The consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
3. The malfunction results in the failure of the device to perform its intended essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness, which could cause or contribute to a death or serious injury.

NOTE: The essential function of a device refers, not only to the device's labeled use, but for any use widely prescribed within the practice of medicine.

4. The malfunction involves a long-term implant or a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life. Malfunctions of long-term implants are not routinely or "automatically" reportable unless the malfunction is likely to cause or contribute to a death or serious injury if it recurs.
5. The manufacturer takes or would be required to take an action under sections 518 or 519(f) of the Act as a result of the malfunction of the device or other similar devices.

Conversely, malfunctions ARE NOT REPORTABLE if they are not likely to result in a death, serious injury, or another malfunction.

SOURCES OF INFORMATION

WHERE TO OBTAIN MDR FORMS

1. Consolidated Forms and Publications Distribution Center
Beltsville Service Center
6351 Ammendale Road
Beltsville, MD 20715
NOTE: Form FDA 3500A ONLY
2. Division of Small Manufacturers, International and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
1350 Piccard Drive (HFZ 220)
Rockville, MD 20850
NOTE: AVAILABLE ONLY THROUGH FACTS-ON-DEMAND SYSTEM
3. Food and Drug Administration
MedWatch (HF-2)
5600 Fishers Lane, Room 17-65
Rockville, MD 20857
1-800-FDA-1088 (Press "0" to speak with a staff member) or 301-827-7240
NOTE: FORM FDA 3500 ONLY
4. Reporting Systems Monitoring Branch
Division of Surveillance Systems
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive (HFZ-533)
Rockville, MD 20850
NOTE: FDA FORMS 3500A, 3417, and 3419 and instructions for each
5. Web pages

<http://www.fda.gov/medwatch> and click on "How to Report".

<http://www.fda.gov/cdrh/mdr.html>

The instructions for the Mandatory MedWatch Form, 3500A, are located at –
<http://www.fda.gov/medwatch/report/instruc.htm>.

WHERE TO SUBMIT ALL MANDATORY MDR REPORTS

Food and Drug Administration
 Center for Devices and Radiological Health
 PO Box 3002
 Rockville, MD 20847-3002

NOTE: Envelopes must be specifically identified with the type of report enclosed, e.g., Manufacturer Report, User Facility Report, Baseline Report, Annual Report, Five-Day Report, Supplemental Report, etc.,

WHERE TO OBTAIN MDR FORMS, GUIDANCE DOCUMENTS OR OTHER MDR INFORMATION

1. CDRH Facts-On-Demand, telephone number 1-800-899-0381 or 301-827-0111. After connecting, follow the recorded instructions. The system allows for one request per call. Enter the shelf number of choice from the list below followed by the # (pound) sign and continue with the programmed prompts.

MDR DOCUMENTS FROM FACTS-ON-DEMAND SYSTEM

- | <u>SHELF NO.</u> | <u>TITLE</u> |
|------------------|--|
| 336# | Final MDR Regulation, published 12/11/95 |
| 407# | Baseline Report, FDA Form 3417 |
| 409# | User Facility Annual Report, FDA Form 3419 |
| 799# | MDR Related Documents Information |
| 853# | Instructions and Coding Manual for MedWatch 3500A, 77 pages |
| 854# | MedWatch, FDA Form 3500A |
| 1061# | Instructions for completing FDA Form 3417, Baseline Report |
| 1096# | Stay of effective date for denominator data on Baseline Report |
| 1336# | Amendment to final rule, Federal Register, 4/11/96 |
| 1853# | Coding Manual Addendum |
2. Reporting Systems Monitoring Branch
 Division of Surveillance Systems
 Office of Surveillance and Biometrics
 Center for Devices and Radiological Health
 1350 Piccard Drive (HFZ-533)
 Rockville, MD 20850
Fax: 301-837-0008 (specify the documents needed and include your address and a phone number where you can be reached) or phone 301-594-2735
 3. FDA Internet Home Page (HP)

<http://www.fda.gov> - once connected select the CDRH icon.

<http://www.fda.gov/cdrh> - CDRH home